

## **REMARKS/ARGUMENTS**

The applicants thank the Examiner for his consideration of the application. Claims 1-3 and 23-29 are pending in the application.

### **Double Patenting**

Claims 1-3 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-3 in U.S. Patent No. 6,464,667. The applicant submits herewith a terminal disclaimer to overcome a non-statutory obviousness type double patenting rejection of claims 1-3 in view of 1-3 of U.S. Patent No. 6,464,667.

### **35 U.S.C. §102**

The Examiner rejected claims 1-3 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,496,273 issued to Pastrone et al. ("Pastrone"). The applicants have amended claim 1 such that the method includes providing a disposable cassette having (i) a liquid inlet for receiving a supply of liquid, (ii) at least two vial receptacles, and (iii) a chamber for receiving a drug from at least one vial receptacle and for receiving liquid from the liquid supply. Pastrone does not disclose, teach or suggest such a disposable cassette.

Pastrone discloses a drug infusion system that includes a plurality of separate pumping cassettes. Each pumping cassette includes a primary inlet port, a secondary inlet port, and an outlet port. (Col. 2, lines 51-61, Fig. 1). Each pumping cassette is in valved communication with a fluid line that leads to a manifold. (Col. 2, lines 35-44, Fig.1). Thus, each of Pastrone's pumping cassettes is capable of receiving two fluids at any given instance. Claim 1 of the present application, as amended, includes a disposable cassette which is capable of receiving two or more medications (via the at least two vial receptacles) as well as a fluid through the fluid inlet. Thus, two (or more) medications may be mixed in a chamber in the cassette at any given instance with a fluid, an additional substance, thereby mixing three (or more) substances together. It is not possible to mix three or more substances in a chamber in one of Pastrone's pumping cassette at any given instance because each pumping cassette has only two inlets for receiving liquids. Accordingly, Pastrone is not capable of reconstituting two powdered medications, for example. Consequently, the subject matter of claim 1 (and claims 2 and 3 which depend from claim 1) is not anticipated or rendered obvious by Pastrone.

New claim 23 of the present application is directed to a method for preparing an intravenous drug in a vial that includes attaching a vial containing a powdered drug to the vial receptacle, introducing a volume of liquid into the vial and causing the liquid to flow between the vial and the chamber to mix the powdered drug with the volume of liquid. There is no disclosure, teaching or suggestion in Pastrone with respect to mixing powdered drugs with a volume of liquid. Thus, new claim 23 (and claims 24-26 which depend from it) is not anticipated or rendered obvious by Pastrone.

New claim 27 is directed to a method for preparing an intravenous drug in a vial which includes providing a disposable cassette having a liquid inlet, a vial receptacle, a mixing chamber and a delivery chamber in communication with an outlet port. Both the mixing chamber and the delivery chamber are in valved communication with the inlet port. (Thus, both the mixing chamber and the delivery chamber may receive fluid from the inlet port without the fluid going into the other chamber.) A volume of liquid is measured in the delivery chamber and the volume is caused to flow to the mixing chamber. The volume of liquid is introduced into the vial and caused to flow between the vial and the mixing chamber to create a mixture.

The features of new claim 26 permit a user to introduce any desired amount of liquid the mixing chamber for mixing with some other substance. In accordance with the present invention drugs may be diluted in a correct amount so as to avoid sending to the patient a drug solution that is too concentrated or too diluted. To ensure the correct amount of dilution, liquid from the IV solution source is measured in the delivery chamber before being sent to the mixing chamber. (Page 6, lines 12-17). In contrast, Pastrone describes a single chamber in the cassette. Even if the reservoir of the Pastrone cassette could be considered a chamber, it is not possible to fill the pumping chamber without first filling the reservoir because there is only one fluid inlet and it leads first to the reservoir. Consequently, the subject matter of claim 26 is not anticipated by Pastrone and, indeed, Pastrone teaches away from the subject matter of claim 26 because the reservoir must be filled before in order to fill the pumping chamber. Thus, claim 26 and (claims 27 and 28 which depend from claim 26) is not anticipated or rendered obvious by Pastrone.

### CONCLUSION

The applicants believe that no fees are due at this time. If any fees are required for the timely consideration of this application, please charge deposit account number 19-4972. All the claim rejections have been addressed. Reconsideration of the application and issuance of a notice of allowance are respectfully requested.

Respectfully submitted,



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